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EXAMINER	
POUS, NATALIE R	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,000	CHANDUSZKO, ANDRZEJ J.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/1/06, 6/28/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS cont: 2/28/05, 1/21/05*.

DETAILED ACTION

Response to Arguments/Remarks

Regarding the 35 USC 112 rejections

1. Examiner acknowledges the amendment to claim 24 to include the recitation "orthogonal to the axis of the center joint." This is sufficient to overcome the 112-second paragraph rejection of claims 24-26, and as such that rejection is withdrawn.

Regarding the Huebsch Patent

2. Applicant's arguments filed April 24, 2006 regarding the Huebsch patent have been fully considered but they are not persuasive. Applicant asserts that Huebsch does not disclose an anchor member "comprising a generally cylindrical member," and that the "cylindrical shaft" of the Huebsch patent refers to almost the entire device as configured in the delivery catheter and not to an anchor member. And further, that the anchor member of Huebsch is formed of "struts 22" radially emanating from the axis of the device. Examiner asserts that the language of claim 1 recites "wherein anchor member of at least one of said first and second sides comprises a generally cylindrical member." To clarify, reference to character "12" is found only in figure 2, and was is referenced illustratively to point applicants attention to "one of said first and second sides." Whether or not the rest of the device is cylindrical in shape does not have bearing on the first or second end comprises a cylindrical member.

3. Next applicant asserts that Huebsch does not teach "wherein each of said first and second sides includes an anchor member comprising a generally cylindrical member split along a portion of its length to form an elongate oval." Examiner disagrees with this position. Huebsch teaches wherein each end of the device (generally sides 14 and 16) have anchor members (defined by portions 22) comprising a generally cylindrical member (as illustrated in figure 2) that is split along the central portion of its length (split between portions 22) to form an elongate oval (as seen in figure 3). It is noted that claim 1 recites "a device for closing a defect in septal tissue comprising:" The term "comprising" means that any prior art must comprise *at least* the limitations as set forth in the claim. Each slit in the anchor members is along a central longitudinal plane of the device, and therefore, Huebsch meets the limitations as set forth in the claims.

4. Examiner sustains that Huebsch does meet the limitations of claims 1 and 20, and as such sustains the prior 35 U.S.C. 102(b) rejections of claims 1-9, 12, 15-25 and 27-32, and further rejects claims 34 and 35 as being anticipated by Huebsch.

5. Based on the sustained 102(b) rejections, the prior 35 U.S.C. 103(a) rejections of claims 11, 13, 14, 26 and 33 are also sustained.

Regarding the Sideris patent

6. Applicant's arguments, see page 8 of the remarks, filed April 24, 2006, with respect to the rejection(s) of claim(s) 20 and 34-38 under 35 USC 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of a new interpretation of the previously applied reference. Paragraph 101 of the application states that the purpose of the "open" configuration of the anchor members as being formed from cylindrical members is that "this configuration increases the size and surface area of the anchor member, thereby improving the dislodgement resistance of the closure device." Although Sideris does not teach wherein the anchors comprise cylinders split along the center, Sideris does teach an open configuration with a large anchor member surface area, which would improve dislodgement resistance of the closure device. It would have been an obvious matter of design choice to provide Sideris with anchor members formed from cylinders split along the central portions of their lengths, since the device of Sideris performs the same function.

Priority

7. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120, 121, or 365(c) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application Nos. 10/326535 and 60/340858, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The cited applications do not have support for the limitation "wherein the anchor member of at least one of said first and second sides comprises a generally cylindrical member split along the central portion of its length to form an elongate oval," required by the independent claims of the present application. Accordingly, claims 1-38 are not entitled to the benefit of the prior applications.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-9, 12, 15-25 and 27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Huebsch et al (US 5853422).

Regarding Claim 1, Huebsch teaches a device for closing a defect in septal tissue, comprising: a first side (14) adapted to be disposed on one side of the septal tissue and a second (16) side adapted to be disposed on the opposite side of the septal tissue, said first and second sides connected by at least one center joint (18), wherein each of said first and second sides includes an anchor member (22), and wherein the anchor member of at least one of said first and second sides comprises a generally

cylindrical member (12) split along the central portion of its length (20) to form an elongate oval (Fig. 3).

Regarding Claim 2, Huebsch teaches the device of Claim 1, wherein said at least one center joint (18) extends through the defect in the septal tissue (6) when said device is deployed at its intended delivery location.

Regarding Claim 3, Huebsch teaches the device of Claim 2, wherein said first and second sides cooperate to provide a compressive force to the septal tissue surrounding the defect (Column 4, proximate lines 39-46).

Regarding Claim 4, Huebsch teaches the device of Claim 1, wherein each of said first and second sides comprises a generally cylindrical member split along the central portion of its length to form an elongate oval (Fig. 3).

Regarding Claim 5, Huebsch teaches the device of Claim 4, wherein said first and second anchor members (14, 16) are three-dimensional.

Regarding Claim 6, Huebsch teaches the device of Claim 1, wherein said anchor members include a material selected from the group consisting of metals, polymers, shape memory materials, bioresorbable materials, drug-exuding materials, and combinations of the foregoing materials (Column 2, proximate lines 37-40).

Regarding Claim 7, Huebsch teaches the device of Claim 1, wherein said at least one center joint includes a stretchable elastomeric material (Column 3, proximate lines 49-63).

Regarding Claim 8, Huebsch teaches the device of Claim 7, wherein said at least one center joint includes a shape memory material (Column 3, proximate lines 64-67).

Regarding Claim 9, Huebsch teaches the device of Claim 8, wherein said at least one center joint includes nitinol (Column 3, proximate lines 64-67).

Regarding Claim 10, Huebsch teaches the device of Claim 9, wherein said at least one center joint comprises a nitinol film (Column 4, proximate lines 3-10).

Regarding Claim 12, Huebsch teaches the device of Claim 7, wherein said at least one center joint includes a material that promotes closure of the defect in the septal tissue (Column 7, proximate lines 44-56).

Regarding Claim 15, Huebsch teaches the device of Claim 1, wherein at least one of said first and second anchor members (14, 16) includes a tissue scaffold (22).

Regarding Claim 16, Huebsch teaches the device of Claim 15, wherein said tissue scaffold includes a material selected from the group consisting of polyester fabrics, Teflon-based materials, ePTFE, polyurethanes, metallic materials, polyvinyl alcohol (PVA), extracellular matrix (ECM), synthetic bioabsorbable polymeric scaffolds, collagen, drug-exuding materials, and combinations of the foregoing materials (Column 2, proximate lines 37-40).

Regarding Claim 17, Huebsch teaches the device of Claim 15, wherein each of said first and second anchor members (14, 16) includes a tissue scaffold.

Regarding Claim 18, Huebsch teaches the device of Claim 17, wherein said at least one center joint (18) is connected to said tissue scaffolds (22).

Regarding Claim 19, Huebsch teaches the device of Claim 1, wherein said device is retrievable. It is noted that any implanted medical prosthesis or implant may be retrieved by a number of means.

Regarding Claim 20, Huebsch teaches a device for closing a defect in septal tissue, comprising: a first side (14) adapted to be disposed on one side of the septal tissue and a second side (16) adapted to be disposed on the opposite side of the septal tissue, said first and second sides connected by a at least one center joint (18), wherein each of said first and second sides includes an anchor member (22) comprising a generally cylindrical member (12) split along the central portion of its length (20) to form an elongate oval, and wherein said first and second sides cooperate to provide a compressive force to the septal tissue surrounding the defect when said device is deployed at an intended delivery location (Column 4, proximate lines 39-46).

Regarding Claim 21, Huebsch teaches the device of Claim 20, wherein said anchor members include a material selected from the group consisting of metals, polymers, shape memory materials, bioresorbable materials, drug-exuding materials, and combinations of the foregoing materials (Column 2, proximate lines 37-40).

Regarding Claim 22, Huebsch teaches the device of Claim 21, wherein each of said elongate oval anchor members (22) is three-dimensional.

Regarding Claim 23, Huebsch teaches the device of Claim 22, wherein each of said elongate oval anchor members (22) is configured to minimize the septal profile of said device.

Regarding Claim 24, Huebsch teaches the device of Claim 23, wherein the arcs of said elongate oval anchor members are positioned at an angle θ from the plane of said device orthogonal to the axis of the center joint.

Regarding Claim 25, Huebsch teaches the device of claim 24, wherein each of said elongate oval anchor members (22) is concave in shape.

Regarding Claim 27, Huebsch teaches the device of Claim 20, wherein each of said first and second anchor members includes a tissue scaffold (22).

Regarding Claim 28, Huebsch teaches the device of Claim 27, wherein said tissue scaffold includes a material selected from the group consisting of polyester fabrics, Teflon-based materials, ePTFE, polyurethanes, metallic materials, polyvinyl alcohol (PVA), extracellular matrix (ECM), synthetic bioabsorbable polymeric scaffolds, collagen, drug-exuding materials, and combinations of the foregoing materials (Column 2, proximate lines 37-40).

Regarding Claim 29, Huebsch teaches the device of Claim 20, wherein said at least one center joint includes a stretchable elastomeric material (Column 3, proximate lines 49-63).

Regarding Claim 30, Huebsch teaches the device of Claim 29, wherein said at least one center joint includes a shape memory material (Column 3, proximate lines 64-67).

Regarding Claim 31, Huebsch teaches the device of Claim 30, wherein said at least one center joint includes nitinol (Column 3, proximate lines 64-67).

Regarding Claim 32, Huebsch teaches the device of Claim 29, wherein said at least one center joint includes a material that promotes closure of the defect in the septal tissue (Column 7, proximate lines 44-56).

Regarding Claim 34, Huebsch teaches the device of claim 20, further comprising a retrieval mechanism for retrieving said device from its intended delivery location (Column 6, proximate lines 9-13)

Regarding Claim 35, Huebsch teaches the device of claim 34, wherein said retrieval mechanism reduces the profile of said device such that said device may drawn into a catheter (Column 6, proximate lines 9-13).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 13 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch in view of Hannam (US 5649959). Huebsch teaches all aspects of preceding dependent claims as previously described, but Huebsch does not disclose using glue, thrombogenic materials, or growth factors to accelerate tissue ingrowth, but Hannam discloses a similar anchor member 30 (see Fig. 12) and teaches injecting such

materials (fibrin glue, cyanoacrylate, etc.) (column 8 lines 32-47) in conjunction with plug 30 in order to form a blood clot more quickly and allow the tissue to heal more quickly. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to apply fibrin glue to Huebsch's closure device in order to more rapidly form a blood clot (column 8 line 55),

as taught by Hannam.

12. Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch in view of Kanesaka et al (US 5776183). Huebsch teaches all aspects of preceding dependent claims 1 and 7, but fails to disclose wherein said at least one center joint is porous or comprises holes. Kanesaka teaches a medical prosthesis comprising pores to absorb or retain a drug for slow release. It would have been obvious to on one of ordinary skill in the art at the time the invention was made to modify the device of Huebsch with a porous material as taught by Kanesaka in order to slowly release a drug into the tissue.

13. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch as a matter of design choice. Huebsch teaches all aspects of preceding claims 20-24 as previously described, but fails to disclose wherein said angle θ is greater than 0 degrees and less than about 45 degrees. It would have been obvious to one of ordinary skill in the art at the time the invention was made to configure angle θ to be greater than 0 degrees and less than about 45 degrees since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum workable ranges involves only ordinary skill in the art. In re Aller, 105 USPQ 233.

14. Claims 1-3, 5-7, 19-24, 29, 34-36 rejected under 35 U.S.C. 103(a) as being unpatentable over Sideris (US 5284488) as a matter of design choice.

Sideris teaches a device for closing a defect in septal tissue comprising the following:

- a first side (34) adapted to be disposed on one side of the septal tissue
- a second side (38) adapted to be disposed on the opposite side of the septal tissue
- said first and second sides connected by a at least one center joint (42), wherein each of said first and second sides includes an anchor member (34, 38) having an elongate oval shape (column 5 proximate lines 25-30
- and wherein said first and second sides cooperate to provide a compressive force to the septal tissue surrounding the defect when said device is deployed at an intended delivery location (Column 3, proximate lines 30-43).
- a retrieval mechanism (18, 44) for retrieving said device from its intended delivery location.
- said retrieval mechanism reduces the profile of said device such that said device may drawn into a catheter (fig. 4).
- said retrieval mechanism reduces the distance between said first and second anchor members and aligns said first and second anchor members in a longitudinal orientation (fig. 4).
- said retrieval mechanism comprises a string extending from one end of said first anchor member to and through said second anchor member (44), and a ball

constrained on said string within said second anchor member (connection of string 44 to skeleton wire 40). It is noted that according to Merriam Webster, the definition of ball is as follows: a round or roundish body or mass. Further, the knot or tie at the connection of the string 44 to skeleton wire 40 is roundish.

- said string (44) is flexible. It is noted that string (44) is comprised of nylon thread, which is inherently flexible.
- the center joint (42) extends through the defect in the septal tissue when said device is deployed at its intended delivery location.
- wherein said first and second anchor members (34, 38) are three-dimensional.
- anchor members include a material selected from the group consisting of metals, polymers, shape memory materials, bioresorbable materials, drug-exuding materials, and combinations of the foregoing materials (Column 4, proximate lines 40-43).
- at least one center joint includes a stretchable elastomeric material (Column 3, proximate lines 1-6).
- each of said elongate oval anchor members (34, 38) is configured to minimize the septal profile of said device.
- the arcs of said elongate oval anchor (34, 38) members are positioned at an angle θ from the plane of said device orthogonal to the axis of the center joint.

Sideris fails to teach the anchors comprising a generally cylindrical member split along the central portion of its length. It would have been an obvious matter of design choice to form the anchor members from generally cylindrical members split along the

center portion of their length, since applicant has not disclosed that such a configuration provides any advantage over the configuration of Sideris, and it appears the anchor members of Sideris perform the task of increasing the size and surface area of the anchor member, thereby improving the dislodgement resistance of the closure device equally well as that disclosed in the application.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
6/16/06

(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER

6/23/06